

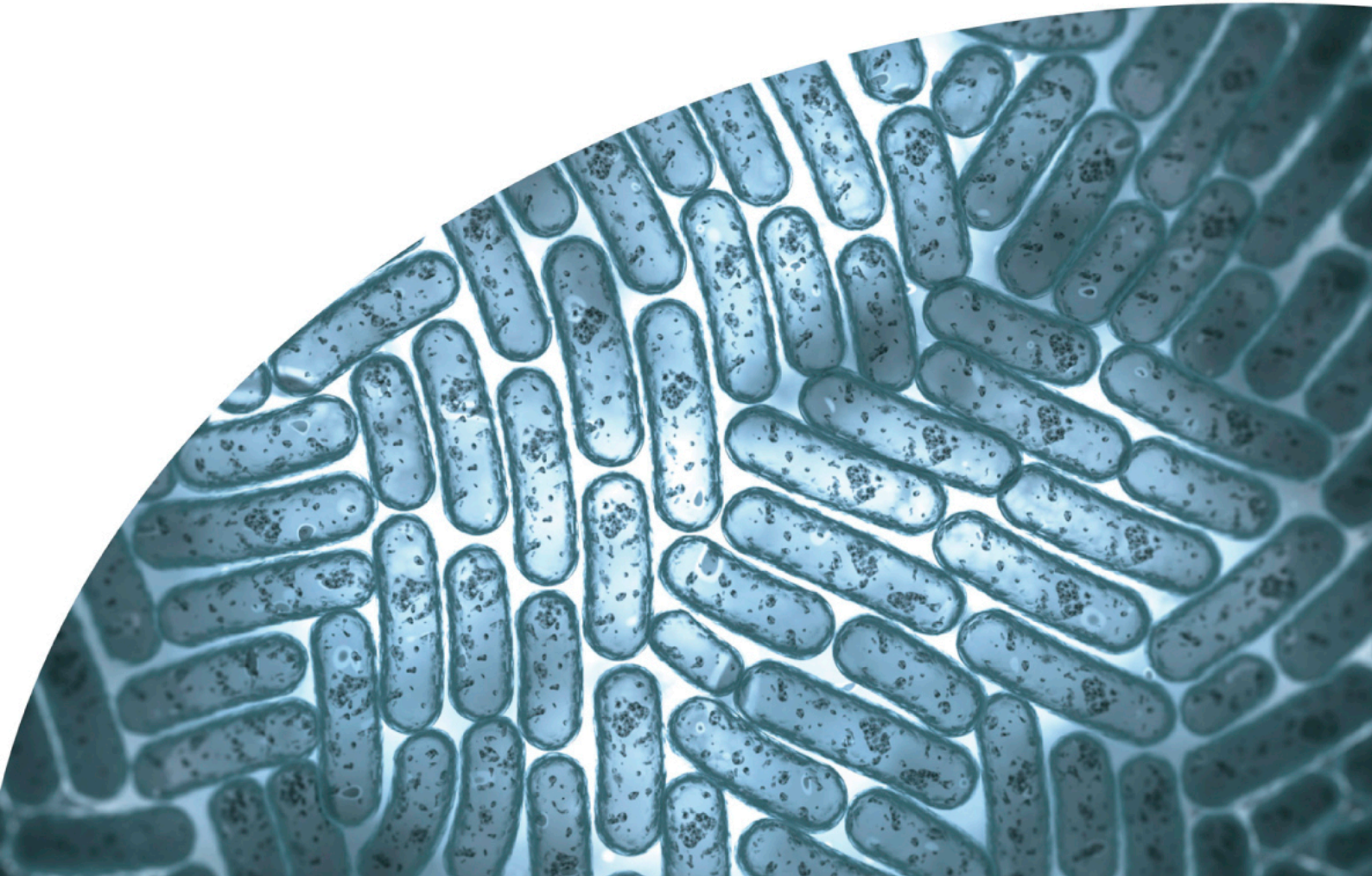


The Results

Using technology to help fight infection

HCAI Technology Innovation Programme
Showcase Hospitals report number 9

Sage 2% Chlorhexidine Gluconate Cloth



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Policy	Clinical	Estates
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Document Purpose	Gathering INFORMATION
Gateway Reference	17736
Title	HCAI Technology Innovation Programme Showcase Hospitals report number 9 Sage 2% Chlorhexidine Gluconate Cloth
Author	Department of Health
Publication Date	June 2012
Target Audience	PCT Cluster CEs, NHS Trust CEs, SHA Cluster CEs, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, Directors of Finance, GPs, Emergency Care Leads, Directors of Infection Prevention and Control
Circulation List	
Description	This document reports on the in use evaluation of the Sage 2% Chlorhexidine Gluconate Cloth in selected Showcase Hospitals and includes a template business case for use in any Trust considering using this product.
Cross Ref	N/A
Superseded Docs	N/A
Action Required	N/A
Timing	N/A
Contact Details	Procurement, Investment and Commercial Division Department of Health 2a Castle View House Runcorn WA7 2GJ
For Recipient's Use	

The Healthcare Associated Infections (HCAI) Technology Innovation Programme

The basic ways of preventing and reducing healthcare associated infections (HCAIs) are largely unchanging. The principal strategies for combating HCAIs are those associated with hand hygiene/aseptic techniques, prudent antibiotic prescribing and good clinical practice. However, new technologies and equipment can support these strategies by helping get things done differently, more swiftly or more reliably.

The Department of Health has funded the HCAI Technology Innovation Programme¹. The Programme aims to

- Speed up the development and adoption of technologies to further help combat HCAIs
- Identify which new technologies provide the best value and will have the most impact

The Showcase Hospitals Programme

In 2004 the Department of Health set up the Rapid Review Panel (RRP) to “provide a prompt assessment of new and novel equipment, materials and other products that may be of value to the NHS in improving hospital infection control and reducing hospital acquired infection”. The RRP does not undertake any product trials itself but makes recommendations based on written evidence provided by industry.² The highest recommendation (Recommendation 1) is

Basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.

As part of the HCAI Technology Innovation Programme, technologies which have gained a RRP Recommendation 1 are being placed in Showcase Hospitals around the country whilst a detailed evaluation of their in-use and economic features along with adoption characteristics is undertaken. The Showcase Hospitals are The Royal Wolverhampton Hospitals NHS Trust, Imperial College Healthcare NHS Trust, Calderdale and Huddersfield NHS Foundation Trust, Southampton University Hospitals NHS Trust, County Durham and Darlington NHS Foundation Trust, The Lewisham Hospital NHS Trust, Mid Essex Hospitals NHS Trust, Central Manchester University Hospitals NHS Foundation Trust, and Hull and East Yorkshire Hospitals NHS Trust.

These are service evaluations, as defined by the National Patient Safety Agency's National Research Ethics Service, and do not therefore require Research Ethics Committee review³.

¹ For further information on the Programme see <http://www.hcai.dh.gov.uk>

² For more information on the Rapid Review Panel see

<http://www.hpa.org.uk/ProductsServices/InfectiousDiseases/ServicesActivities/RapidReviewPanel/rapAboutRRP/>

³ See leaflet on defining research at <http://www.nres.npsa.nhs.uk/news-and-publications/publications/general-publications/#leaflets>

Acknowledgements

We would like to acknowledge the support of staff working at the participating Showcase Hospitals in evaluating the Sage 2% Chlorhexidine Gluconate Cloth.

Additionally, we acknowledge the specialist support of the NHS Technology Adoption Centre, Health Protection Agency and the Deputy Director of Infection Prevention and Control at Imperial Healthcare College NHS Trust in the compilation of this report.

Showcase Hospitals Technology Review report number 9

Sage 2% Chlorhexidine Gluconate (CHG) Cloth

Contents

Executive summary	6
Introduction	7
The problem	7
Surgical site infections are a significant cause of healthcare associated infections (HCAIs) in Caesarean Section Delivery patients	7
The product	
Sage 2% Chlorhexidine Gluconate Cloths	8
The knowledge base	
What was known before this evaluation	9
The evaluation	
How the evaluation was done	9
Does the product reduce infections?	10
When is the best time to use the product?	13
Advice for Trusts considering introducing the Sage 2% Chlorhexidine Gluconate Cloth	
Important points to consider	13
Costs and benefits	14
Drawing up a business case	15
References	18

Executive summary

The Department of Health has set up a Rapid Review Panel (RRP) to assess new and novel technologies and consider their potential for reducing hospital infections. As part of the Department's Healthcare Associated Infections (HCAI) Technology Innovation Programme, technologies that have received an RRP1 recommendation ("basic research and development, validation and in-use evaluations have shown benefits that should be available to NHS bodies") have been placed in selected Showcase Hospitals for review of their acceptability in everyday use and to gather information that may be useful for other hospitals.

Sage 2% Chlorhexidine Gluconate (CHG) cloths are intended for patient use to clean their skin prior to surgery. They received an RRP 1 recommendation in April 2008.

Sage 2% CHG cloths were used prior to caesarean section delivery (CSD) in seven Showcase Hospitals for four months. The overall rate of Surgical Site Infections (SSIs) following CSD fell from 10.4% to 7.6% with use of the Sage 2% CHG cloths, a reduction in incidence of 27%. After adjusting for variables associated with SSI rates and allowing for differences in follow-up times, the reduction was 39%.

The Sage 2% CHG cloth was used prior to CSD during this evaluation, but given the SSI reductions observed, it should be noted that the product can be used in many other areas in the health setting, particularly the surgical patient care pathway.

The evaluation has identified that although the application of the Sage 2% CHG cloth may have been inconsistent due to the emergency nature of the some of the patient group, the outcome has still demonstrated a significant decrease in the occurrence of SSIs in relation to CSD. This may result in benefits across a broad range of areas within the health sector. In the community, there is likely to be a decrease in the requirement for antibiotics thus reducing the risk of antimicrobial resistance. From a care management perspective, the decrease in SSI would reduce General Practitioner consultations, treatment and prevent extended Community Midwife visits post delivery.

From a separate HPA study, it is known that a small percentage of patients are readmitted with significant SSI of their abdominal wound. This intervention may assist in reducing this occurrence with the financial cost saving benefits being seen in the secondary setting.

The decision to implement this product is a local one but a template business case has been produced to assist providers considering its use.

Keywords: Chlorhexidine gluconate; caesarean section; surgical site infections

Introduction

This report sets out the findings from an evaluation that has been conducted at The Royal Wolverhampton Hospitals NHS Trust, Imperial College Healthcare NHS Trust, Calderdale and Huddersfield NHS Foundation Trust, County Durham and Darlington NHS Foundation Trust, The Lewisham Hospital NHS Trust, Mid-Essex Hospitals NHS Trust and Hull and East Yorkshire Hospitals NHS Trust of the efficacy and economic features of the Sage 2% Chlorhexidine Gluconate (CHG) Cloth.

The Rapid Review Panel which assesses new and novel products which may help infection prevention and control has concluded that basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols.

The objective of this document is to help Directors of Infection Prevention and Control and other stakeholders to decide whether they should consider introducing the Sage 2% CHG Cloth as part of their Trust's strategy to prevent surgical site infections.

The problem

Surgical site infections are a significant cause of healthcare associated infections (HCAs) in Caesarean Section Delivery patients

Surgical site infections (SSIs) are a significant cause of healthcare associated infections (HCAs). SSIs account for 15% of all HCAs and are associated with considerable morbidity and estimated to double the length of hospital stay.^[i] This evaluation focused in particular on caesarean section deliveries (CSDs).

The number of mothers who have a CSD has increased in recent years. Approximately one baby in four born in the UK is delivered by caesarean section.^[ii] Women who undergo CSD are 5 times more likely to develop postpartum infection after delivery than women who undergo vaginal delivery.^[iii] Rates of SSI following CSD of between 11 and 18% have been reported, with 84 % of these cases identified post-discharge.^[iv]

SSIs associated with CSD usually consist of 2 types: (1) endometritis which results in bacteria being introduced into the uterine cavity; and (2) infection of the surgical incision site.^[v]

Whilst most infections are minor, SSI following CSD can have far reaching implications for the woman and her family in terms of morbidity and socioeconomic consequences^[vi] and even the most minor infections are likely to lead to the prescribing of antibiotics and additional involvement of community midwives.

In some cases the infection results in readmission and associated increased costs to the healthcare system. The HPA recently undertook a separate study of SSI occurrence in 2167 CSD patients. Of those 2167 patients, 65 (3%) were readmitted with 33 of the 65 patients (51%) having an SSI^[vii].

The product

Sage 2% Chlorhexidine Gluconate (CHG) Cloths



Sage 2% CHG cloths come in a 6-cloth single pack for individual patient use which is intended to provide a cloth for each area of the body for a patient to prepare with prior to surgery. The packs are available in cases consisting of 40 packs, and were supplied for the evaluation at a cost of £221 (including VAT), which equates to a patient pack cost of £5.15.

Sage state that the 2% CHG cloth:

- Helps reduce bacteria that can cause skin infection. Provides rapid bactericidal action. Has persistent antimicrobial effect (at least 6 hours) against a wide variety of microorganisms. Remains active in the presence of blood and other organic matter.
- Reduces bacteria on the skin, which can help reduce risk of transmitting microorganisms from patients to staff, other patients, visitors, and surrounding environment.
- Is alcohol-free and skin-friendly. Won't dry out skin like alcohol-based antiseptics. Soothes and moisturizes skin with aloe.
- Large, premoistened washcloths require no rinsing. Ensures consistent chlorhexidine coverage while reducing mess and waste. Makes it easier to cleanse difficult to reach areas such as skin folds.
- Ready to use right from the package. No diluting or additional supplies needed.
- Non-abrasive, textured washcloth provides gentle yet effective scrubbing action to remove dirt and debris.
- Delivers comforting warmth for patients when warmed in product warming device
- Latex Free

The Sage 2% CHG cloth received an RRP 1 recommendation in April 2008, but did not become eligible for evaluation in the showcase hospitals until it received its Marketing Authorisation (MA) as a medicinal product from the Medicines and Healthcare products Regulatory Agency (MHRA) in July 2010.

The knowledge base

What was known before this evaluation

Two key strategies for reducing the risk of SSI by minimising the contamination of the operative site from micro-organisms derived from the skin are pre-operative showering and the application of antiseptics at the operative site immediately prior to incision. In the peri-operative period the NICE guidelines 74 (October 2008) ^[viii] recommend preparation of the skin at the surgical site immediately before incision using an antiseptic preparation such as povidone-iodine or CHG. The guidelines noted that most studies were of insufficient sample size and tested different combinations of antiseptic and therefore clear data on their efficacy was not available at the time of review. A subsequent study ^[ix] demonstrated a significant reduction in risk of SSI associated with 2% CHG alcoholic solution used for skin preparation compared to povidone-iodine.

In the pre-operative period the NICE clinical guidelines recommend a shower or bath using soap either the day before or on the day of surgery as a mechanism of minimising skin contamination. Whilst the review of evidence considered studies that used skin antiseptics such as CHG, there was insufficient evidence to show a statistically significant difference in effect on the risk of SSI between showering using CHG or soap ^[x]. Subsequent guidelines issued by the Canadian initiative 'Safer Healthcare Now' ^[xi] in 2010 report three recent research studies that demonstrated a reduced risk of SSI associated with 2% CHG impregnated washcloths used in combination with other strategies to prevent SSI ^{[ix][xii] [xiii]}. There is also other evidence to support the role of 2% CHG washcloths in reducing other healthcare associated infections when used for daily cleansing and cost effectiveness in SSI reduction in other types of surgery ^{[xiv][xv]}.

The evaluation

How the evaluation was done

As part of the Showcase Hospitals programme, Sage 2% CHG cloths were introduced for four months in selected NHS hospitals with the aim of evaluating their effectiveness by measuring the occurrence of SSI. The surveillance methodology was based on the Health Protection Agency's surveillance of SSI following CSD. Data were collected and entered on surveillance data sheets by designated trained staff, with SSI data being collected either whilst the woman was still in hospital or by the Community Midwife.

Baseline information on SSI occurrence in CSD patients was collected from December 2010 until March 2011 (the pre-intervention period).

From 7 March 2011 to 30 June 2011 (the intervention period) the product was placed into the Showcase Hospitals and all patients undergoing a CSD were asked to use the Sage 2% CHG cloths prior to their surgery. The product was intended for use on the night before and morning of surgery as a preparatory application for surgery, but not as a formal pre-op procedure. The product was intended for use on all areas of the body in accordance with the manufacturer's instructions. In the event, practice varied, and the impact of this is considered further later in this report. Following admission, all patients underwent local preoperative skin disinfection at the time of incision regardless of whether the Sage 2% CHG washcloth was used.

It should be noted that if it was not possible to bathe the patient with the Sage 2% CHG cloths due to an immediate threat to the life of the woman or foetus (National Confidential Enquiry into Patient Outcome and Death (NCEPOD) classification⁴) or other clinical factors then this was clearly noted on the data capture system.

4364 women undergoing CSDs were observed within the study. Of these, 1671 (38.3%) women underwent a CSD during the pre-intervention period, of which 738 (44%) were classed as an emergency CSD. 2693 (61.7%) women underwent CSD in the intervention period, of whom 1460 (54.2%) received the Sage 2% CHG cloth prior to surgery. 1222 (45%) procedures in the intervention periods were classed as an emergency CSD (NCEPOD levels 1&2), and in only 32 % of these procedures was the Sage cloth used. In the remaining non-emergency CSD, 74% used the sage cloth. This report focuses on the differences in rates of SSI between the 1460 women who received the cloth and the 2904 that did not.

This report presents the main findings from this evaluation. A more detailed analysis of the results will be contained in a paper currently being prepared for submission to a peer-reviewed journal.

Does the product reduce surgical site infections?

Overall, 413 women (9.5%) developed a total of 415 SSIs. Figure 1 shows the type of SSI detected. The overwhelming majority (89.4%) were superficial wound infections. Only 12 of the infections developed during hospital admission. The remainder developed post discharge.

⁴ The NCEPOD classification system recommended the categorisation of operations into four grades of urgency. The categories are:

1. Immediate threat to the life of the woman or foetus
2. Maternal or foetal compromise which was not immediately life-threatening
3. No maternal or foetal compromise but needs early delivery
4. Delivery timed to suit woman or staff

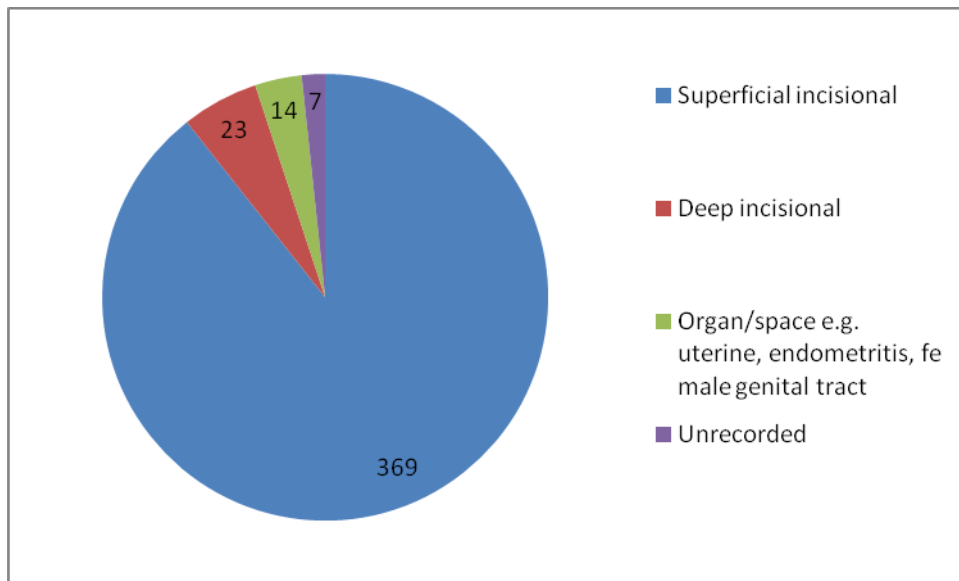


Figure 1: Distribution of SSI by infection type

There were 389 infections for which a time to onset can be calculated. The median time to onset was 10 days, with a quarter of infections developing within the first week, and three quarters of infections developing within two weeks (Figure 2).

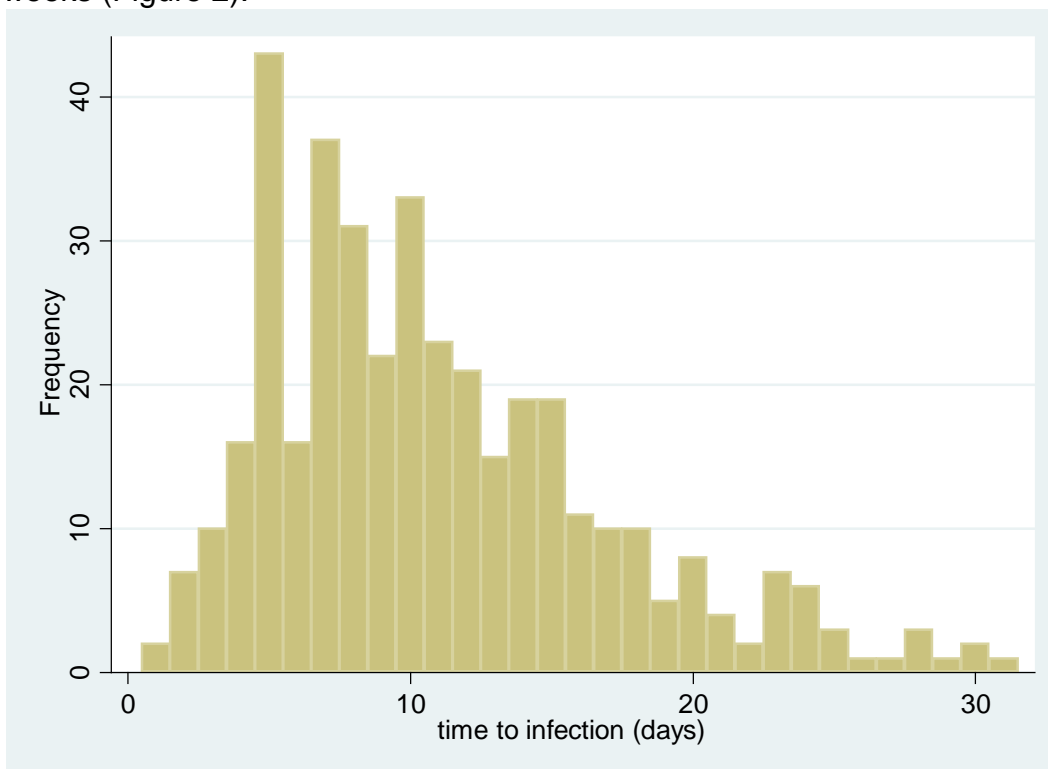


Figure 2: Distribution of the time to infection

Figure 3 compares the rate of SSI in those women who were washed with the Sage 2% CHG cloth with those who received the normal pre-admission guidance as part of their procedure. The rate of SSI in the patients not washed with Sage 2% CHG cloths was 10.4%. The rate of SSI in patients

receiving the Sage 2% CHG cloth treatment was 7.6%, a reduction in incidence of 27%.

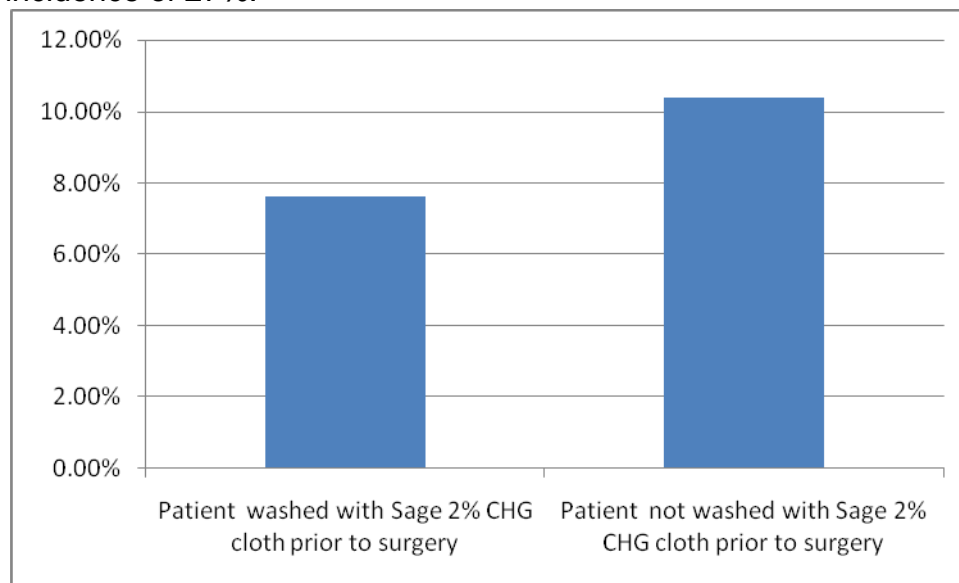


Figure 3: Rates of infection with and without Sage 2% CHG cloth use

Table 1 shows the rates of SSI by Trust. As can clearly be seen, infection rates ranged from 3.2% to 22.6%. Average follow up times also differed between the Trusts. For example, at Trust C nearly all women were followed up for a period close to the 30 day maximum, compared with a median of 10 – 15 days for the other Trusts, and this Trust had by far the highest rate of infection. Therefore, some of these observed differences in rates could be attributed to an ascertainment bias. There was no evidence to suggest that the reduction in SSI rates in patients where the Sage 2% CHG cloth was used differed across the seven Trusts, and the observed variation may be expected by chance alone given the relatively small numbers of SSI at some Trusts.

Trust	SSI (rate)	SSI rate (without use of Sage, %)	SSI rate (with use of Sage, %)	median duration of follow up (days)
A	11.5%	11.60%	11.40%	14
B	13.0%	14.10%	9.70%	11
C	22.6%	23.60%	20.00%	29
D	4.9%	5.70%	3.60%	10
E	8.7%	9.60%	5.50%	15
F	3.4%	3.80%	2.80%	11
G	10.5%	10.40%	10.60%	14
All Trusts	9.5% (413 in total)			

Table 1: Comparison of rates of SSI with and without the use of Sage 2% CHG cloths, by Trust.

When the figures were looked at in more detail, there were many variables that were associated with SSI rates (body mass index, length of operation, wound closure method, surgeon grade, number of previous CSD, age, Sage 2% CHG cloth used the night before surgery and Trust), but there were no obvious differences in the reduction of SSI rates in different sub-sets, when patients who did or did not use the cloth were compared.

Further analysis of the data has been undertaken⁵ to take account of the variation in factors that were associated with SSI rates and to allow for the different follow up times in each woman. The analysis was based on 3264 (75%) of the women in the study, the remaining 1100 women being excluded on the basis that information was missing on at least one of the variables in the regression model. This analysis indicates an estimated reduction in the risk of developing infection of 39%, compared with the 27% shown in figure 3. This increase in effect is probably due to taking account of the variation in length of follow-up and SSI rate between Trusts.⁶

When is the best time to use the product?

The variations in rates of SSI between Trusts make it difficult to look at the issue of the best time to use the Sage 2% CHG cloths. The lowest rate was achieved if patients were washed with the cloth only prior to surgery (4.7%), rather than the night before only (6.7%). The highest rate (11.6%) was in those patients who were washed with the cloths both the night prior to and the morning of surgery.

The most important point to note, however, is that women who washed with the Sage 2% CHG cloth the night before surgery do not appear to have had a decreased rate of SSI. The study results do suggest that optimal results were related to using the cloth close to the time of surgery.

Advice for Trusts considering introducing the Sage 2% Chlorhexidine Gluconate (CHG) cloth

Important points to consider

Trusts considering introducing the Sage 2% CHG cloth will need to assess when it is likely to be of maximum benefit in terms of reducing SSIs. There is some evidence from this review to support – and certainly nothing to contradict – the view taken in the Canadian guidelines that bathing or showering is the most cost effective approach to general preparation for surgery, but that the use of chlorhexidine cloths may be of value in reducing the risk of SSI when used as close to the time of surgery as possible.

⁵ A multivariable Poisson regression model was used.

⁶ It should be noted that 7.5% of excluded women developed an SSI post CSD, compared with 10.1% of those included in the model, suggesting that the excluded women could not be considered to be missing at random. However, the unadjusted estimate of the reduction in risk in those women receiving the Sage cloth was similar in the two sub-groups of women included in and excluded from the model, at 27.3% and 26.8%, respectively.

This study looked at the use of Sage 2% CHG cloths prior to CSD. We have no direct evidence from this evaluation regarding the efficacy of Sage 2% CHG cloths in reducing SSIs following other types of surgery. The studies cited earlier suggest, however, that the cloths could well be effective in reducing SSIs in other types of surgery and it seems likely that other surgical interventions could benefit from the use of this product.

Costs and Benefits

If Sage 2% CHG cloths are used in addition to the existing pre-operative skin disinfection procedure, the additional cost per patient of the product is £5.15 (price at the time of the evaluation). Against this must be set the savings from reducing the number of SSIs.

The outcome of the evaluation has shown that in patients who did not receive the cloth as part of their procedural preparations, 10.4% experienced an SSI. With those patients who used the Sage cloth, there was a 27% reduction in rate of SSI to 7.6%. A 39% reduction was found when other factors associated with the risk of SSI, variation in SSI rates and different periods of post-operative follow up were taken into account.

Savings resulting from this reduction in SSIs will arise in both hospital and community settings, and these will be considered in turn.

In this study, 12 out of 415 SSIs (2.9%) developed during hospital admission and may have led to additional costs, although, since most (89.4%) of SSIs were superficial wound infections, the savings from reducing the number of such infections may not be significant.

A recent HPA study of SSI occurrence in the CSD patient was conducted across a group of 2167 patients. Of those 2167 patients, 65 (3%) were readmitted with 33 of the 65 patients (51%) having an SSI^[vii]. Such readmissions obviously lead to additional costs in the hospital sector.

As an example, if 1000 patients used 1000 packs of the product costing £5150, then a 27% reduction would mean that 28 fewer women developed an SSI, 1 less SSI would be detected during admission and 4 readmissions would be prevented. A 39% reduction would mean 41 fewer women developed an SSI, 1 less SSI would be detected during admission and 6 readmissions would be prevented.

Calculation of savings associated with these reductions is probably best based on local data, but, for example, a Showcase Hospital participating in the evaluation stated that their non-elective spell tariff for CSD with complications is £887 higher than for a standard CSD, and the tariff for a readmission for complications of a procedure is £1,091.

Savings in the community from reduced numbers of SSIs are likely to arise from earlier discharge time from the midwives, reduced GP involvement and

reduced prescribing of antibiotics. Assigning cash figures to these savings can only be done locally, as there is no information available centrally to enable quantification of the savings.

In addition to direct financial savings, reductions in SSIs have other benefits. For example, along with the clinical benefit to the patient with the reduced risk of SSI, any reduction in the use of antibiotics is desirable from the point of view of the risk of antimicrobial resistance. There are also benefits to the reputation of the NHS service provider.

Drawing Up A Business Case

Decisions on the use of this product must be made locally.

Trusts may wish to adopt and adapt the following model when drawing up a business case for this product. Text in italics (other than the section headings) gives information about how to complete the business case. Text in ordinary font (and the section headings) is intended to be suitable for cutting and pasting into the business case. The symbol ♥ indicates where numbers need to be inserted.

Because this report focuses on CSDs, this outline business case does so too. We have no direct evidence from this evaluation regarding the efficacy of Sage 2% CHG cloths in reducing SSIs following other types of surgery, but Trusts may wish to consider using the cloths more widely on a trial basis, conducting their own evaluations to see whether reductions in SSI rates are observed.

The problem

The number of mothers who have a caesarean section delivery (CSD) has increased in recent years. Approximately one baby in four born in the UK is delivered by caesarean section. Women who undergo a CSD are 5 times more likely to develop postpartum infection after delivery than women who undergo vaginal delivery. Rates of SSI following CSD of between 11 and 18% have been reported, with 84 % of these cases identified post-discharge.

Uterine related SSI usually consist of 2 types: (1) endometritis which results from the introduction of bacteria into the uterine cavity; and (2) infection of the surgical incision site, Although it seldom represents a threat to life, SSI following CSD can have far reaching implications for the woman and her family in terms of morbidity and socioeconomic consequences.

In this Trust, ♥ women undergo a CSD each year (of whom ♥ undergo a CSD as an emergency procedure) and ♥ [are estimated to] develop an SSI. *Insert information from local surveys, being sure to include as far as possible information about infections which develop post discharge, as this is likely to be the case for the overwhelming majority of infections. So far as possible, distinguish between the numbers of superficial infections which are treated*

with antibiotics in the community and the numbers of more serious infections which may delay discharge or require (or extend the duration of) readmissions.

Sage 2% Chlorhexidine Gluconate (CHG) cloths

Sage 2% CHG cloths come in a 6-cloth single pack for individual patient use which is intended to provide a cloth for each area of the body for a patient to prepare with prior to surgery. The use of CHG to minimise the risk of SSI through reducing microbial contamination at the operative site has been recognised as an important strategy to prevent SSI and a number of studies demonstrating the efficacy of Sage cloths have been reported (ref to NICE and Canada) An evaluation of the use of Sage 2% CHG cloths prior to CSD, undertaken in England under the Department of Health's HCAI Technology Innovation programme, showed a reduction of 27% in SSIs post CSD, or 39% if other factors associated with SSI and variations in follow-up time were taken into account.

The cloths are probably most effective when used as close in time to surgery as possible, and they are therefore perhaps likely to be less used when CSDs are undertaken as an emergency procedure.

Costs and Benefits

The cost of a single pack of Sage 2% CHG cloths is £5.15 (cost at the time of the evaluation). If ♥% of women undergoing a CSD were to use the cloths [*bear in mind that perhaps 70% of women undergoing a CSD in an emergency and perhaps 20% of other women may not use the cloths*] the total costs would be [*take the total number of women undergoing CSDs at the Trust and multiply by the percentage that may use the cloths and **the cost per pack***].

The financial savings may be calculated as follows.

(a) Savings in the community. *Take the number of infections treated in the community with antibiotics (likely to be around 90%), apply an appropriate percentage reduction, or a range of such reductions – perhaps 25% to 40% - and multiply the resulting figure by the cost of treating these infections in the community.*

(b) Savings in hospital costs. *Assemble as much information as possible about the costs of treating the remaining infections (there may be some additional costs in the community too, in which case they will need to be included in section (a)) and once again apply an appropriate percentage reduction or a range of such reductions.*

In addition to the financial savings, there are, of course, other benefits to be borne in mind, notably the reduction in pain and discomfort resulting from reduced numbers of infections.

Conclusions and Recommendation

Taking action to reduce SSIs following CSD is desirable in order to reduce harm to patients and increase confidence in the safety of the services provided by the Trust. In our Trust ♥ patients undergo CSDs and ♥% of them develop an SSI.

Use of Sage 2% CHG cloths prior to CSD has been shown in a number of studies to reduce the rate of SSIs. The analysis above suggests that *insert results of cost benefit analysis.*

The options are

- Continue current practice. This incurs no additional costs but results in no additional benefits.
- Introduce Sage 2% CHG cloths for women about to undergo a CSD. *Summarise costs and benefits.* The incidence of SSIs will [continue to] be monitored and the use of the cloths kept under review.
- As above, but consider also introducing the cloths more widely prior to surgery. This would be in the context of an evaluation of their efficacy in reducing SSIs. If this option is favoured, further more detailed proposals will be drawn up in parallel with the introduction of the cloths for CSD.

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